IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Customer No.:	
Group:	3733
Confirmation No.:	9399
Application No.:	10/667,685
Invention:	MODIFIED SYSTEM AND METHOD FOR INTRAOPERATIVE TENSION ASSESSMENT DURING JOINT ARTHROPLASTY
Applicant:	Mark A. Heldreth
Filed:	September 22, 2003
Attorney Docket:	DEP777USNP
Examiner:	Anuradha Ramana

DATED: April 24, 2009

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

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Sir:

This Appeal Brief is submitted electronically in support of the appeal from the Primary Examiner's September 2, 2008 final rejection of claims 1-4, 10, 12-17 and 28-37, and is submitted within two months of the February 27, 2009 filing date of the Notice of Appeal. Please charge Deposit Account No. 10-0750/DEP777USNP/SJM with reference to our matter DEP777USNP in the amount of $540 for the fee to file this Appeal Brief. It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be

charged, or any overpayment in fees be credited, to Deposit Account No. 10-0750/DEP777USNP/SJM with reference to file DEP777USNP.

REAL PARTY IN INTEREST

The real party in interest is DePuy Products, Inc., the assignee, pursuant to an assignment recorded in the records of the U. S. Patent and Trademark Office at reel 014537, beginning at frame 0073.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants that will directly affect or be directly affected by, or have a bearing on the Board's decision in the present appeal.

STATUS OF CLAIMS

Claims 1-4, 10, 12-17 and 28-37 were finally rejected in the Office Action dated September 2, 2008.

Claims 5-9, 11 and 18-27 were cancelled.

Each of claims 1-4, 10, 12-17 and 28-37 is appealed.

A copy of pending claims 1-4, 10, 12-17 and 28-37 is attached hereto in an Appendix.

STATUS OF AMENDMENTS

Appellant has filed no amendments subsequent to the September 2, 2008 final rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1:

The invention of claim 1 is for a system for balancing soft tissue intraoperatively during total joint arthroplasty through use of two trials: an instrumented trial 10A, 10B, 10C, 10D, 10E, 10F for one of the bones and a trial 12A, 12B, 12C, 12D, 12E, 12F that is not instrumented for the other bone. (see, for example, page 9, lines 3-8) The system of claim 1 encompasses trials

for use in knee arthroplasty, as shown in FIGS. 1-3, 7, 9-10 and 11-14 and described generally at pages 9-18, for use in hip arthroplasty, as shown in FIG. 18 and described at pages 18-19, for use in shoulder arthroplasty, as shown in FIG. 20 and described at pages 19-20, and for use in wrist arthroplasty, as shown in FIG. 23 and described at page 20, for example.

The instrumented trials 10A-10F are joint trials 30A-30F having an articulating surfaces with curved contours. (see, for example, page 13, lines 7-12; page 16, lines 2-6). For example, the curved concave contour of the proximal articulating surface 38 of a tibial insert trial 30A is shown in FIGS. 1-3, 7, 9-10 and 11-14. The curved concave contour of the articulating surface of an acetabular liner trial 30D is shown in FIG. 18 and described at page 18, lines 10-12. The curved convex contour of the articulating surface of a humeral head trial 30E is shown in FIG. 20 and described at page 19, lines 8-10. The curved concave contour of the articulating surface of a radial trial 30F is shown in FIG. 23 and described at page 20, lines 4-6.

The mating trials 12A-12F of each illustrated system also have articulating surfaces with curved contours. (see, for example, page 9, lines 15-21) For example, the curved convex contour of the distal articulating surfaces 14, 16 of a distal femoral trial 12A is shown in FIG. 4 and described at page 9, lines 15-16. The curved convex contour of the articulating surface of a proximal femoral head trial 12D is shown in FIG. 19 and described at page 18, lines 12-13. The curved concave contour of the articulating surface of a glenoid trial 12E is shown in FIG. 21 and described at page 19, lines 10-11. The curved convex contour of the articulating surface of a metacarpal trial 12F is shown in FIG. 23 and described at page 20, lines 7-8.

The curved contour of the articulating surface of the first joint trial 30A-30F is shaped to receive the articulating surface of the second joint trial 12A-12F. For example, surface 38 of

tibial insert 30A is shaped to receive the condyles 14, 16 of the distal femoral component 12A. (see, for example, page 9, lines 20-21; page 17, lines 17-19)

Each of the illustrated systems encompassed by claim 1 also include a flexible sensor array and a protector. (see, for example, page 9, lines 21-22) The sensor arrays are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 26A, 26D, 26E and 26F associated with trials 30A-30F. The protectors are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 28A, 28B, 28C, 28D, 28E and 28F.

The sensor arrays 26A, 26D, 26E and 26F are capable of being shaped to define a curved contour and are capable of generating a signal in response to pressure (see, for example, page 11, line 18 – page 12, line 5). In claim 1, the sensor array has a portion that is shaped to define a concave curved contour and an opposite surface that has a convex curved contour, as illustrated in FIGS. 1-3, 9-14, 17, 18, 20 and 23.

The protectors 28A, 28B, 28C, 28D, 28E and 28F have surfaces with curved concave contours (such as surface 34) and opposite surfaces with curved convex contours (such as surface 36), as illustrated in FIGS. 1-3, 5, 9-15, 18, 20 and 23 and described at page 13, lines 7-12. The protectors 28A-28F are capable of transmitting pressure to the sensor array (see, for example, page 13, lines 14-17). Each protector 28A-28F has a thickness between the curved concave contour 34 and the curved convex contour 36 (see, for example, page 13, lines 18-20: FIGS 2-3, 5, 10-11, 13-14, 18, 20 and 23). The curved contour of the articulating surface 38 of the first joint trial and the curved contoured surfaces (e.g. 34, 36) of the protector are curved in a plurality of intersecting cross-sections (see, for example, for the knee arthroplasty system, FIGS 2-3, 9, 11, 13-14).

In each of the illustrated embodiments, the sensor array 26A, 26D, 16E, 26F is removable from the associated trial 10A-10F and the protector 28A-28F without damaging the sensor array (see, for example, page 4, lines 17-18 and page 10, lines 4-6, for example).

Complementary mounting members are associated with the protector 28A-28F and the first joint trial 30A-30F for temporarily securing the sensor array 28A, 26D-26F between the protector 28A-28F and the first joint trial 30A-30F. (see page 14, lines 12-18, page 20, lines 10-12)

Examples of complementary mounting members include studs: 46, 48 and complementary holes 40, 42; studs 52, 54 that mate with apertures or holes 56, 58 in the insert trial 30B; and stud 84 and aperture 86. (see, for example, page 14, line 12 – page 15, line 14, page 17, lines 20-24; FIGS. 1-4, 5-7 and 9-11).

The complementary mounting members limit movement of the protector 28A-28F with respect to the first joint trial 30A-30F during use. Thus, the position of the protector 28A-28F is fixed relative to the articulating surface (e.g. surface 38) of the first joint trial 30A-30F during use. (see, for example, page 15, lines 15-19)

The complementary mounting members are sized, shaped and positioned so the protector 28A-28F and the sensor array 26A, 26D-25F may be temporarily secured on the curved contour of the articulating surface (e.g. surface 38) of the first joint trial 30A-30F with the sensor array 26A, 26D-26F positioned between the curved contours of the articulating surface (e.g. 38) of the first joint trial 30A-30F and the curved contoured opposite surface (e.g. 36) of the protector 28A-28F. (see, for example, page 15, line 15 - page 16, line 6; page 24, line 18 – page 25, line 11; FIGS. 2-3, 10-11, 13-14, 18, 20 and 23).

Dependent Claim 28:

Claim 28 depends on claim 1 and adds that the articulating surface 38 of the first joint trial 30A-30D and 30F is concave and the articulating surface of the second joint trial 12A, 12D, 12F is convex. These features of the first joint trial 30A-30D and 30F are illustrated in FIGS. 2-3, 10-11, 13-14, 18 and 23 and described, for example, in the specification at page 9, lines 18-20; page 11, lines 13-15; page 18, lines 10-12; and page 20, lines 4-6. These features of the second joint trial 12A, 12D and 12F are illustrated in FIGS. 19 and 22 and described in the specification, for example, at page 9, lines 15-16; page 18, lines 12-13; page 20, lines 7-8. Claim 28 further specifies that the complementary mounting members are spaced from the articulating surface 38 of the first joint trial 30A-30D, 30F and the articulating surface (e.g. 34) of the protector 28A-28D, 28F. Example of such positioning are shown in FIGS. 1-3, 5-7, 9-15, 20 and 23. (see, for example, page 16, lines 16-19; page 18, lines 16-22; page 19, lines 14-22). Another example of such a surface is non-articulating surface 96 shown in FIG. 18 and described at page 18, lines 16-19. (see, for example, page 18, lines 16-19).

Dependent Claim 29

Claim 29 depends on claim 28 and adds that the first joint trial 30A-30D includes an additional surface adjacent to the concave articulating surface (e.g. 38) of the first joint trial 30A-30D. One of the complementary mounting members 40, 42, 46, 48, 52, 54, 56, 58, 84, 86 is associated with the additional surface of the first joint trial 30A-30D. Examples of such positioning are shown in FIGS. 1-3, 5-7, 9-15, 20 and 23. (see, for example, page 16, lines 16-19; page 18, lines 16-22; page 19, lines 14-22). Another example of such position is shown in FIG. 18 and described at page 18, lines 16-19. (see, for example, page 18, lines 16-19).

Dependent Claim 30:

Claim 30 depends on claim 29 and adds that the first joint trial 30A-30C includes a second concave articulating surface. The additional surface adjacent to the concave articulating surface is between the two articulating surfaces (e.g. 38) of the first joint trial 30A-30C. These features are illustrated in the embodiments of the tibial trial in FIGS. 1-3, 5-7 and 9-14. (see, for example, page 16, lines 16-19).

Dependent Claim 31:

Claim 31 depends on claim 1 and specifies that the articulating surface 100 of the first joint trial 30E and the articulating surface 104 of the protector 28E are convex and that the articulating surface 102 of the second joint trial 12E is concave. These features are illustrated in the embodiment of FIGS. 20-21 and are described at page 19, line 8 – page 20, line 3. Claim 31 further specifies that the complementary mounting members 112, 113, 114 and 115 are spaced from the articulating surface 100 of the first joint trial 10E and the articulating surface 104 of the protector 28E. These features are illustrated in FIG. 20 and described at page 19, lines 16-22.

Dependent Claim 32:

Claim 32 depends on claim 31 and further specifies that the first joint trial 30E has a periphery and the protector 28E has a periphery and the complementary mounting members 112, 113, 114 and 115 are associated with the peripheries of the first joint trial 30E and the protector 28E. These features are illustrated in FIG. 20 and described at page 19, lines 16-22.

Independent Claim 2:

The invention of claim 2 is for a system for balancing soft tissue intraoperatively during total joint arthroplasty through use of two trials: an instrumented trial 10A, 10B, 10C, 10D, 10E, 10F for one of the bones and a trial 12A, 12B, 12C, 12D, 12E, 12F that is not instrumented for the other bone. (see, for example, page 9, lines 3-8) The system of claim 2 encompasses trials for use in knee arthroplasty, as shown in FIGS. 1-3, 7, 9-10 and 11-14 and described generally at pages 9-18, for use in hip arthroplasty, as shown in FIG. 18 and described at pages 18-19, for use in shoulder arthroplasty, as shown in FIG. 20 and described at pages 19-20, and for use in wrist arthroplasty, as shown in FIG. 23 and described at page 20, for example.

The instrumented trials 10A-10F are joint trials having articulating surfaces with curved contours. (see, for example, page 13, lines 7-12; page 16, lines 2-6; FIGS. 1-3, 7, 9-10, 11-14, 18, 20 and 23). For example, the curved concave contour of the proximal articulating surface 38 of a tibial insert trial 30A is shown in FIGS. 1-3, 7, 9-10 and 11-14. The curved concave contour of the articulating surface of an acetabular liner trial 30D is shown in FIG. 18 and described at page 18, lines 10-12. The curved convex contour of the articulating surface of a humeral head trial 30E is shown in FIG. 20 and described at page 19, lines 8-10. The curved concave contour of the articulating surface of a radial trial 30F is shown in FIG. 23 and described at page 20, lines 4-6.

The mating trials 12A-12F of each illustrated system also have articulating surfaces. (see, for example, page 9, lines 18-21; FIGS. 4, 19, 21 and 22) For example, the distal articulating surfaces 14, 16 of a distal femoral trial 12A are shown in FIG. 4 and described at page 9, lines 15-16. The articulating surface of a proximal femoral head trial 12D is shown in FIG. 19 and described at page 18, lines 12-13. The articulating surface of a glenoid trial 12E is

shown in FIG. 21 and described at page 19, lines 10-11. The articulating surface of a metacarpal trial 12F is shown in FIG. 23 and described at page 20, lines 7-8.

Each of the illustrated systems encompassed by claim 12 also include a flexible sensor array and a protector. (see, for example, page 9, lines 21-22) The sensor arrays are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 26A, 26D, 26E and 26F associated with trials 30A-30F. The protectors are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 28A, 28B, 28C, 28D, 28E and 28F.

The sensor arrays 26A, 26D, 26E and 26F are capable of generating a signal in response to pressure (see, for example, page 11, lines 18-21).

The protectors 28A, 28B, 28C, 28D, 28E and 28F have opposite surfaces: one surface (e.g. 34) is an articulating surface and has a curved contour and the opposite surface (e.g. 36) also has a curved contour, as illustrated in FIGS. 1-3, 5, 9-15, 18, 20 and 23 and described at page 13, lines 7-12. The protectors 28A-28F are capable of transmitting pressure to the sensor array (see, for example, page 13, lines 14-17).

In each of the illustrated embodiments, the sensor array 26A, 26D, 26E, 26F is removable from the associated trial 30A-30F and the protector 28A-28F without damaging the sensor array (see, for example, pages 4, lines 17-18 and page 10, lines 4-6).

Complementary mounting members are associated with the protector 28A-28F and the first joint trial 30A-30F for temporarily securing the sensor array 26A, 26D-26F between the protector 28A-28F and the first joint trial 30A-30F. (see, for example, page 14, lines 12-18, page 20, lines 10-12). The complementary mounting members are positioned so that the protector 28A-28F and the sensor array 26A, 26D-26F may be temporarily secured on the curved contour of the articulating surface (e.g. surface 38) of the trial 30A-30F. The complementary mounting

members limit movement of the protector 28A-28F with respect to the first joint trial 30A-30F during use. Thus, the position of the articulating surface (e.g. 34) of the protector 28A-28F is fixed relative to the articulating surface (e.g. surface 38) of the first joint trial 30A-30F during use. (see, for example, page 15, lines 15-19)

Examples of complementary mounting members include studs: 46, 48 and complementary holes 40, 42; studs 52, 54 that mate with apertures or holes 56, 58 in the insert trial 30B; and stud 84 and aperture 86. (see, for example, page 14, line 12 – page 15, line 14, page 17, lines 20-24; FIGS. 1-4, 5-7 and 9-11).

As best illustrated in FIGS. 12-14, the protector 28C comprises a first portion 74 and a second portion 76 joined along an axis 78. The first portion 74 of the protector 28C overlies at least part of the curved contour of the articulating surface 38 of the first trial 10C and the second portion 76 of the protector 28C overlies at least a substantial part of the sensor array 26A and at least a substantial part of the first portion 74 of the protector 28C. These features of the protector are described in the specification beginning at page 17, line 10 and continuing through page 18, line 2 and at page 21, lines 20-23.

Independent Claim 10:

The invention of claim 10 is for a system for balancing soft tissue intraoperatively during total joint arthroplasty through use of two trials: an instrumented trial 10A-10D for one of the bones and a trial 12A, 12D that is not instrumented for the other bone. (see, for example, page 9, lines 3-8) The system of claim 10 encompasses trials for use in knee arthroplasty, as shown in FIGS. 1-3, 7, 9-10 and 11-14 and described generally at pages 9-18 and systems for hip arthroplasty, as shown in FIGS. 18-19 and described generally at pages 18-19.

The instrumented trials 10A-10D have articulating surfaces with curved concave contours. (see, for example, page 13, lines 7-12; page 16, lines 2-6; page 18, lines 10-12). For example, the curved concave contour of the proximal articulating surface 38 of a tibial insert trial 30A is shown in FIGS. 1-3, 7, 9-10 and 11-14. The curved concave contour of the articulating surface 98 of an acetabular liner trial 30D is shown in FIG. 18. The first joint trials 30A-30D also have surfaces adjacent to the curved concave articulating surfaces (such as surface 38 and surface 98); these adjacent surfaces are illustrated in FIGS. 1-3, 9-14 and 18 and described at page 16, lines 16-19 and page 18, lines 16-19.

The mating trial 12A, 12D of this system also has an articulating surface with a curved convex contour. (see, for example, page 9, lines 18-21 and page 18, lines 12-13; FIG. 19). For example, the curved convex contour of the distal articulating surfaces 14, 16 of a distal femoral trial 12A is described at page 9, lines 15-16 and the curved convex contour of the proximal femoral head trial is shown in FIG. 19 and described at page 18, lines 12-13.

Each of the illustrated systems encompassed by claim 10 also include a flexible sensor array and a protector. (see, for example, page 9, lines 21-22; page 18, lines 10-12) The sensor arrays are illustrated in FIGS. 1-3, 6, 9-14 and 18 at 26A and 26D associated with trials 30A-30D. The protectors are illustrated in FIGS. 1-3, 6, 9-14 and 18 at 28A-28D.

The flexible sensor array 26A, 26D is shaped to define a curved concave contour and is capable of generating a signal in response to pressure (see, for example, page 11, line 18 – page 12, line 5; page 18, lines 16–22; FIGS. 1-3, 9-14 and 18).

The protectors 28A-28D each have a surface (such as surface 34) with a curved concave contour and a surfaces (such as surface 36) with a curved convex contour, as illustrated in FIGS.

1-3, 5, 9-14 and 18 and described at page 13, lines 7-12. The protectors 28A-28D are capable of transmitting pressure to the sensor array (see, for example, page 13, lines 14-17).

The curved convex surface (such as surface 36) of the protector 28A-28D overlies and contacts at least a substantial part of the curved concave contour of the flexible sensor array 26A. This relationship is illustrated in FIGS. 2-3, 10-11, 13-14 and 18. (see, for example, page 14, line 15 – page 15, line 6 and page 24, line 18- page 19, line 11).

The curved concave surface (such as surface 34) of the protector 28A-28D is exposed above the sensor array 26A, 26D and the articulating surface 38, 98 of the first joint trial 10A-10D. (see, for example, FIGS. 2-3, 10-11, 13-14 and 18).

The curved concave surface (such as surface 34) and curved convex surface (such as surface 36) of the protector 28A-28D are curved in a plurality of intersecting cross-sections. (see, for example, FIGS 2-3, 10-11 and 13-14).

In addition, in these embodiments, a stud 46, 48, 52, 54, 84 and 94 extends between the protector 28A-28D and the surface of the first trial 30A-30D that is adjacent to the curved concave articulating surface (for example, surface 34). An example of such an adjacent surface is non-articulating surface 96 shown in FIG. 18 and described at page 18, lines 16-19). Other such surfaces are illustrated, for example, in FIGS. 1-3, 7 and 9-15. The studs 46, 48, 52, 54, 84 and 94 and complementary holes or apertures 40, 42, 56, 58 serve to temporarily fix the position of at least part of the protector with respect to the trial 10A-10C. (see, for example,, for example, page 14, lines 12-18).

Independent Claim 12:

The invention of claim 12 is also for a system for balancing soft tissue during total joint arthroplasty through use of two trials: an instrumented trial 10A, 10B, 10C, 10D, 10E, 10F for one of the bones and a trial 12A, 12B, 12C, 12D, 12E, 12F that is not instrumented for the other bone. (see, for example, page 9, lines 3-8) The system of claim 12 encompasses trials for use in knee arthroplasty, as shown in FIGS. 1-3, 7, 9-10 and 11-14 and described generally at pages 9-18, for use in hip arthroplasty, as shown in FIG. 18 and described at pages 18-19, for use in shoulder arthroplasty, as shown in FIG. 20 and described at pages 19-20, and for use in wrist arthroplasty, as shown in FIG. 23 and described at page 20, for example.

The instrumented trials 10A-10F can include a joint trial 30A-30F having an articulating surface with a curved contour. (see, for example, page 13, lines 7-12; page 16, lines 2-6). For example, the curved concave contour of the proximal articulating surface 38 of a tibial insert trial 30A is shown in FIGS. 1-3, 7, 9-10 and 11-14. The curved concave contour of the articulating surface 98 of an acetabular liner trial 30D is shown in FIG. 18 and described at page 18, lines 10-12. The curved convex contour of the articulating surface of a humeral head trial 30E is shown in FIG. 20 and described at page 19, lines 8-10. The curved concave contour of the articulating surface of a radial trial 30F is shown in FIG. 23 and described at page 20, lines 4-6.

The mating trials 12A-12F of each illustrated system also have articulating surfaces with curved contours. For example, the curved convex contour of the distal articulating surfaces 14, 16 of a distal femoral trial 12A is described at page 9, lines 15-16. The curved convex contour of the articulating surface of a proximal femoral head trial 12D is shown in FIG. 19 and described at page 18, lines 12-13. The curved concave contour of the articulating surface of a glenoid trial 12E is shown in FIG. 21 and described at page 19, lines 10-11. The curved convex

contour of the articulating surface of a metacarpal trial 12F is shown in FIG. 23 and described at page 20, lines 7-8.

Each of the illustrated systems encompassed by claim 12 also include a flexible sensor array and a protector. The sensor arrays are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 26A, 26D, 26E and 26F associated with trials 30A-30F. The protectors are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 28A, 28B, 28C, 28D, 28E and 28F.

The sensor arrays 26A, 26D, 26E and 26F are capable of generating a signal in response to pressure (see, for example, page 11, lines 18-21). In claim 12, the sensor array has a portion that is shaped to define a curved contour, as illustrated in FIGS. 1-3, 9-14, 17, 18, 20 and 23.

The protectors 28A, 28B, 28C, 28D, 28E and 28F have surfaces with curved surface, including one with a curved concave contour (e.g. 34) and one with curved convex contour (e.g. 36), as illustrated in FIGS. 1-3, 5, 9-15, 18, 20 and 23 and described at page 13, lines 7-12. The protectors 28A-28F are capable of transmitting pressure to the sensor array (see, for example, page 13, lines 14-17). Each protector 28A-28F has a thickness between the curved concave contour 34 and the curved convex contour 36 (see, for example, page 13, lines 18-20: FIGS 2-3, 5, 10-11, 13-14, 18, 20 and 23). The thickness of each protector 28A-28F at the curved contoured surfaces (e.g. 34, 36) is less than half the thickness of the first joint trial at the articulating surface (see, for example, page 13, lines 18-21; FIGS. 2-3, 5, 10-11, 13-14, 18, 20 and 23). The curved contour of the articulating surface 38 of the first joint trial and the curved contoured surfaces (e.g. 34, 36) of the protector are curved in a plurality of intersecting cross-sections (see, for example, for the knee arthroplasty system, FIGS 2-3, 9, 11, 13-14).

In each of the illustrated embodiments, the sensor array 26A, 26D, 16E, 26F is positioned between the curved contour of the articulating surface (e.g. 38, 98) of the first joint trial 30A-30F

and the curved contoured surfaces (e.g. 34, 36) of the protector 28A-28F. (see, for example, page 15, lines 19-21; FIGS 2-3, 5, 10-11, 13-14, 18, 20 and 23). The sensor array 26A, 26D, 16E, 26F is separable from the associated trial 30A-30F and the protector 28A-28F both before and after use (see, for example, page 10, lines 4-6).

Positive locating features are provided so that the sensor array 26A, 26D, 16E, 26F is positively located with respect to at least one of the protector 28A-28F and the first trial 30A-30F. (see, for example, page 16, line 20 - page 17, line 9; FIGS 1, 5, 7, 12, 15-17, 18 and 20, 23). The positive locating features include at least one positive locating feature spaced from the curved contour of the articulating surface (e.g., 38, 98) of the first joint trial 30A-30F. (see, for example, page 16, lines 16-19; FIGS 1, 5, 7, 12, 18 and 20, 23). Examples of positive locating features include mating cut-outs 46, 48 and lands 64, 66 (see, for example, page 16, lines 10-15; FIGS. 1, 5, 7 and 12) and a cut-out, shown at 70 in FIG. 16 and described at page 17, lines 2-9.

Dependent Claim 33:

Claim 33 depends on claim 12 and adds that the articulating surface (e.g. 38, 98) of the first joint trial 30A-30D and 30F is concave and the articulating surface of the second joint trial 12A, 12D, 12F is convex. These features of the first joint trial 30A-30D and 30F are illustrated in FIGS. 2-3, 10-11, 13-14, 18 and 23 and described, for example, in the specification at page 9, lines 18-20; page 11, lines 13-15; page 18, lines 10-12; and page 20, lines 4-6. These features of the second joint trial 12A-12D and 12F are illustrated in FIGS. 4, 19 and 22 and described in the specification, for example, at page 9, lines 15-16; page 18, lines 12-13; page 20, lines 7-8. Claim 33 further specifies that the mating members are spaced from the concave articulating surface (e.g 38, 98) of the first joint trial 30A, 30D and the concave articulating surface (e.g. 34) of the

protector 28A, 28D. An example of such positioning is shown in FIGS. 1-3, 5-7, 9-15, 20 and 23. (see, for example, page 16, lines 16-19; page 18, lines 16-22; page 19, lines 14-22). Another example of such a surface is non-articulating surface 96 shown in FIG. 18 and described at page 18, lines 16-19. (see, for example, page 18, lines 16-19).

Dependent Claim 34:

Claim 34 depends on claim 33 and adds that the first joint trial 30A-30D, 30F includes an additional surface adjacent to the concave articulating surface (e.g, 38, 98) of the first joint trial 30A-30D, 30F One of the mating members 40, 42, 46, 48, 52, 54, 56, 58, 84, 86 is associated with the additional surface of the first joint trial 30A-30D, 30F. Examples of such positioning are shown in FIGS. 1-3, 5-7, 9-15, 20 and 23. (see, for example, page 16, lines 16-19; page 18, lines 16-22; page 19, lines 14-22). Another example of such positioning is shown in FIG. 18 and described at page 18, lines 16-19. (see, for example, page 18, lines 16-19).

Dependent Claim 35:

Claim 35 depends on claim 34 and adds that the first joint trial 30A-30C includes a second concave articulating surface. The additional surface adjacent to the concave articulating surface is between the two articulating surfaces 38 of the first joint trial 30A-30C. These features are illustrated in the embodiments of the tibial trial in FIGS. 1-3, 5-7 and 9-14. (see, for example, page 16, lines 16-19).

Dependent Claim 36:

Claim 36 depends on claim 12 and specifies that the articulating surface 100 of the first joint trial 30E and the articulating surface 104 of the protector 28E are convex and that the articulating surface 102 of the second joint trial 12E is concave. These features are illustrated in the embodiment of FIGS. 20-21 and are described at page 19, line 8 – page 20, line 3. Claim 36 further specifies that the mating members 112, 113, 114 and 115 are spaced from the articulating surface 100 of the first joint trial 30E and the articulating surface 104 of the protector 28E. These features are illustrated in FIG. 20 and described at page 19, lines 16-22.

Dependent Claim 37:

Claim 37 depends on claim 36 and further specifies that the first joint trial 30E has a periphery and the protector 28E has a periphery and the mating members 112, 113, 114 and 115 are associated with the peripheries of the first joint trial 30E and the protector 28E. These features are illustrated in FIG. 20 and described at page 19, lines 16-22.

Independent Claim 16:

The invention of claim 16 is for a system for balancing soft tissue intraoperatively during total joint arthroplasty through use of two trials: an instrumented trial 10A, 10B, 10C, 10D, 10E, 10F for one of the bones and a trial 12A, 12B, 12C, 12D, 12E, 12F that is not instrumented for the other bone. (see, for example, page 9, lines 3-8) The system of claim 2 encompasses trials for use in knee arthroplasty, as shown in FIGS. 1-3, 7, 9-10 and 11-14 and described generally at pages 9-18, for use in hip arthroplasty, as shown in FIG. 18 and described at pages 18-19, for use

in shoulder arthroplasty, as shown in FIG. 20 and described at pages 19-20, and for use in wrist arthroplasty, as shown in FIG. 23 and described at page 20, for example.

The instrumented trials 10A-10F are joint trials 30A-30F having articulating surfaces (e.g. 38, 98) with curved contours. (see, for example, page 13, lines 7-12; page 16, lines 2-6; page 18, lines 19-22; page 19, lines 10-12; page 20, lines 4-7; FIGS. 1-3, 7, 9-10, 11-14, 18, 20 and 23). For example, the curved concave contour of the proximal articulating surface 38 of a tibial insert trial 30A is shown in FIGS. 1-3, 7, 9-10 and 11-14. The curved concave contour of the articulating surface of an acetabular liner trial 30D is shown in FIG. 18 and described at page 18, lines 10-12. The curved convex contour of the articulating surface of a humeral head trial 30E is shown in FIG. 20 and described at page 19, lines 8-10. The curved concave contour of the articulating surface of a radial trial 30F is shown in FIG. 23 and described at page 20, lines 4-6.

The mating trials 12A-12F of each illustrated system also have articulating surfaces. (see, for example, page 9, lines 18-21; FIGS. 4, 19, 21 and 22) For example, the distal articulating surfaces 14, 16 of a distal femoral trial 12A are shown in FIG. 4 and described at page 9, lines 15-16. The articulating surface of a proximal femoral head trial 12D is shown in FIG. 19 and described at page 18, lines 12-13. The articulating surface of a glenoid trial 12E is shown in FIG. 21 and described at page 19, lines 10-11. The articulating surface of a metacarpal trial 12F is shown in FIG. 23 and described at page 20, lines 7-8.

Each of the illustrated systems encompassed by claim 12 also include a flexible sensor array and a protector. (see, for example, page 9, lines 21-22) The sensor arrays are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 26A, 26D, 26E and 26F associated with trials 30A-30F. The

protectors are illustrated in FIGS. 1-3, 6, 9-10, 18, 20 and 23 at 28A, 28B, 28C, 28D, 28E and 28F.

The flexible sensor arrays 26A, 26D-26F are shaped to define a curved contour and are capable of generating a signal in response to pressure (see, for example, page 11, line 18 – page 12, line 5; page 18, lines 16–22; FIGS. 1-3, 9-14 and 18).

The protectors 28A, 28B, 28C, 28D, 28E and 28F have opposite surfaces: one surface (e.g. 34) is an articulating surface and has a curved contour and the opposite surface (e.g. 36) also has a curved contour, as illustrated in FIGS. 1-3, 5, 9-15, 18, 20 and 23 and described, for example, at page 13, lines 7-12. The protectors 28A-28F are capable of transmitting pressure to the sensor array (see, for example, page 13, lines 14-17).

The sensor arrays 26A, 26D-26F are positioned between the curved contour of the articulating surface (e.g. 38, 98) of the first joint trial 30A-30F and the curved contoured surface (e.g. 36) of the protector 28A-28F. (see, for example, page 13, lines 18-20; FIGS 2-3, 5, 10-11, 13-14, 18, 20 and 23).

In each of the illustrated embodiments, the sensor array 26A, 26D, 16E, 26F is separable from the associated trial 10A-10F and the protector 28A-28F both before and after use. (see, for example, pages 4, lines 17-18; page 10, lines 4-6; page 23, lines 14-21; page 24, line 18 – page 25, line 11; page 27, line 18 – page 28, line 2).

As best illustrated in FIGS. 12-14, the protector 28C comprises a first portion 74 and a second portion 76 joined along an axis 78. The first portion 74 of the protector 28C overlies at least part of the curved contour of the articulating surface 38 of the first trial 30C and the second portion 76 of the protector 28C overlies at least a substantial part of the sensor array 26A and at least a substantial part of the first portion 74 of the protector 28C. These features of the protector

are described in the specification beginning at page 17, line 10 and continuing through page 18, line 2 and at page 21, lines 20-23.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

This appeal presents three grounds of rejection:

I. Whether claims 2 and 16 are unpatentable under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

II. Whether claims 1, 3, 4, 10, 12-15 and 17 are unpatentable under 35 U.S.C. §102 as being anticipated by Hershberger et al. (U.S. Pat. 5,470,354).

III. Whether claims 28-37 are unpatentable under 35 U.S.C. §103 over Hershberger et al. (U.S. Pat. 5,470,354).

ARGUMENT

I. THE BOARD IS URGED TO REVERSE THE FIRST GROUND OF REJECTION: CLAIMS 2 AND 16 MEET THE STANDARD OF DEFINITENESS UNDER 35 USC §112, SECOND PARAGRAPH.

A proper rejection under §112 has not been established in regard to independent claims 2 and 16 for at least the following reasons: the Examiner has applied the incorrect legal standard in rejecting claims 2 and 16; and/or the Examiner has failed to establish that claims 2 and 16 apprise one of ordinary skill in the art of their scope.

The Examiner's basis for rejecting claims 2 and 16 is the Examiner's view that "it is unclear how the second portion of the protector overlies the first portion when the system is in an assembled configuration."

MPEP §2173.02 provides:

"In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine *whether the claim apprises one of ordinary skill in the art of its scope* and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also In re Larsen, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the Larsen claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112 paragraph 2.). See also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ('The requirement to 'distinctly' claim means that *the claim must have a meaning discernible to one of ordinary skill* in the art when construed according to correct principles...Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.')."

Independent Claim 2:

In the case of claim 2, the claim recites that the protector element "comprises a first portion and a second portion joined along an axis, and wherein the first portion of the protector overlies at least a part of the curved contour of the articulating surface of the first trial and the second portion overlies at least a substantial part of the sensor array and at least a substantial part of the first portion of the protector." Thus, the claim clearly encompasses a clam-shell type of structure for the protector, with the sensor array sandwiched between the two portions of the protector, as shown for example in FIG. 12. The Examiner has not stated that one of ordinary skill in the art would be unable to discern the meaning of the claim. And it is difficult to conceive how one of ordinary skill in the art would fail to understand that the claim encompasses a structure where the second portion of the protector overlies the first portion when the system is in an assembled state.

Consider a box with a hinged lid set on a table and an object in the box: two portions of the box (the body and the lid) are joined along an axis (the hinge); at least one portion of the box overlies the table; and when closed, the second portion of the box (the lid) overlies the object in the box and at least part of the other portion (the body) of the box. One of ordinary skill in the art would understand this structure and relationship and would be able to discern the meaning of claim 2.

Independent Claim 16:

Claim 16 similarly calls for the protector to have "a first portion and a second portion joined along an axis, wherein the first portion of the protector overlies at least part of the curved contour of the articulating surface of the first trial and the second portion overlies at least a

substantial part of the sensor array and a substantial part of the first portion of the protector." The above argument with respect to claim 2 applied equally to claim 16. One of ordinary skill in the art would be able to discern the meaning of claim 16.

Accordingly, the Examiner's final rejection of claims 2 and 16 under 35 USC §112, second paragraph, is in error.

Conclusion regarding claims 2 and 16

Based on the above, the Examiner has not established a proper §112 rejection with regard to Appellant's claims 2 and 16. As such, the rejection of claims 2 and 16 should be reversed.

II. THE BOARD IS URGED TO REVERSE THE SECOND GROUND OF REJECTION: CLAIMS 1, 3, 4, 10, 12-15 AND 17 DO NOT READ ON HERSHBERGER ET AL. (U.S. PAT. 5,470,354).

A. Independent Claim 1

A proper rejection under §102 has not been established in regard to independent claim 1 for at least the following reasons: the Examiner failed to consider all of the elements of claim 1; and/or the Examiner failed to identify all of the elements of claim 1 in the cited art.

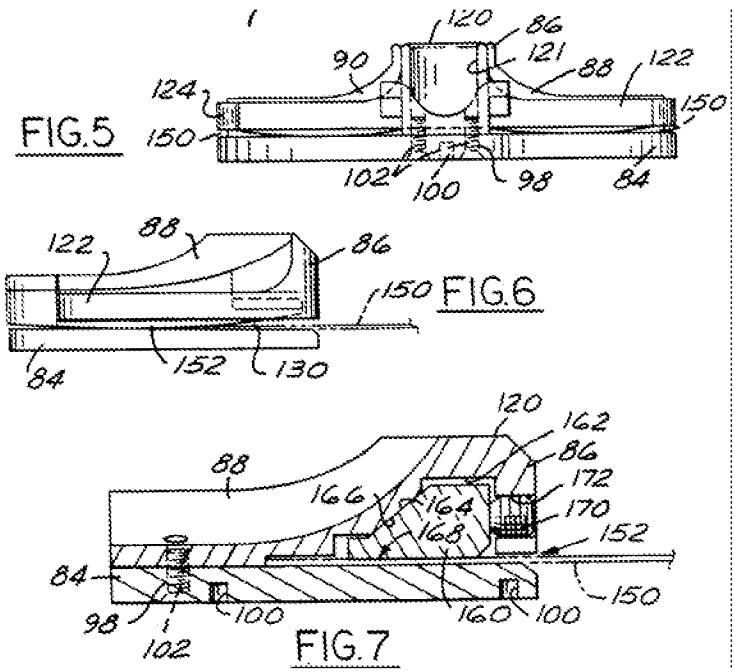
Claim 1 is written in the form set forth in 37 CFR §1.75(e). As set forth in MPEP §608.01(m): "The preamble of this form of claim is considered to positively recite and clearly include all of the elements or steps recited therein as part of the claimed combination." The preamble of claim 1 relates to the invention of Ray C. Wasielewski described in U.S. Pat. App. Ser. No. 10/667,763, entitled "Apparatus, System and Method for Intraoperative Performance Analysis During Joint Arthroplasty[1]," assigned to the assignee of the present application.

[1] U.S. Pat. App. Ser. No. 10/667,763 was rejected on 12-19-2008.

The Federal Circuit held in *Epcon Gas Sys. Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 61 U.S.P.Q.2D 1470 (Fed. Cir. 2002) that "the preamble is a limitation in a Jepson-type claim." ("Jepson form allows a patentee to use the preamble to recite elements or steps of the claimed invention which are conventional or known." [citation omitted] However, in *Rowe v. Dror*, this court stated that "when this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope." [citation omitted]. According to *Rowe* and *Kegel*, the fact that the patentee has chosen the Jepson form of the claim evidences the intention "to use the preamble to define, in part, the structural elements of his claimed invention." *Id.*; [citation omitted] Thus, the preamble is a limitation in a Jepson-type claim. [citations omitted]")

The preamble of claim 1 recites two implant trials as elements, and includes the following recitation: "the curved contours of the articulating surface of the first joint trial and the curved contoured surfaces of the protector being curved in a plurality of intersecting cross-sections, the modified system comprising...."

In the final rejection, the Examiner characterized element 150 as a sensor array and element 84 as a joint trial in Hershberger et al. Although FIG. 3 of Hershberger et al. illustrates a curved periphery of element 84 in plan view, as can be seen from FIGS. 5-7 of Hershberger et al., this element has a flat articulating surface, not one that is curved in a plurality of intersecting cross-sections. The curved edge of Hershberger et al. element 84 (see FIG. 3) cannot be considered to comprise an articulating surface – nothing articulates against it. Accordingly, the Examiner has misinterpreted Hershberger et al. or has failed to consider all of the elements of claim 1; Hershberger et al. does not disclose the invention of claim 1, and does not anticipate claim 1.



Therefore, dependent claims 3-4 and 28-32 are also patentable over Hershberger et al.

Conclusion regarding claims 1, 3-4, and 28-32

Based on the above, the Examiner has not established a proper §102 rejection with regard to Appellant's claim 1. As such, the rejection of independent claim 1, and claims 3-4 and 28-32 depending either directly or indirectly from claim 1, should be reversed.

B. Independent Claim 10

A proper rejection under §102 has not been established in regard to independent claim 10 for at least the following reasons: the Examiner failed to consider all of the elements of claim 10 in making the rejection; and/or the Examiner failed to identify all of the elements of claim 10 in the cited art in making the rejection.

Independent claim 10 also recites that the system includes two trials: a first joint trial having an articulating surface with a curved concave contour and a surface adjacent to the curved concave articulating surface; and a second joint trial having an articulating surface with a curved

convex contour. As set forth in claim 10, the flexible sensor array is shaped to define a curved concave contour. The flexible sensor array is contacted by the curved convex surface of the protector, which overlies and at least a substantial part of the curved concave contour of the flexible sensor array.

In contrast to the invention of claim 10, Hershberger et al. teaches a system wherein a curved surface contacts a flat surface. The surface of the sensor/transducer 150 of FIG. 3 that contacts the element above it is flat: the sensor/transducer 150 is not shaped to define a contour that is curved in a plurality of intersecting cross-sections. Hershberger et al. expressly teaches at col. 6, lines 59-60: "The surfaces are flat and smooth in order to provide a satisfactory surface for the force transducer to contact." Accordingly, the Examiner has misinterpreted Hershberger et al. or has failed to consider all of the elements of claim 10; Hershberger et al. does not anticipate claim 10.

Conclusion regarding claim 10

Based on the above, the Examiner has not established a proper §102 rejection with regard to Appellant's claim 10. As such, the rejection of independent claim 10 should be reversed.

C. Independent Claim 12

A proper rejection under §102 has not been established in regard to independent claim 12 for at least the following reasons: the Examiner failed to consider all of the elements of claim 12; and/or the Examiner failed to identify all of the elements of claim 12 in the cited art.

Independent claim 12 calls for the system to include a protector having a surface with a curved concave contour and a surface with a curved convex contour. The protector has a thickness between the curved concave contour and the curved convex contour; the thickness of

the protector at the curved contoured surfaces is less than half the thickness of the first joint trial at the articulating surface. In addition, claim 12 calls for the sensor array to be positioned between the curved contour of the articulating surface of the first joint trial and the curved contoured surfaces of the protector. The curved contour of the articulating surface of the first joint trial and the curved contoured surfaces of the protector are curved in a plurality of intersecting cross-sections. As discussed above with respect to claim 1, element 84 of Hershberger et al., characterized by the Examiner as the trial, does not have a surface with a curved contour that is curved in a plurality of intersecting cross-sections. Therefore, the Examiner has misinterpreted Hershberger et al. or has failed to consider all of the elements of claim 12; Hershberger et al. cannot anticipate claim 12 or its dependent claims 13-15, 17 or 33-37.

Conclusion regarding claims 12-15, 17 and 33-37

Based on the above, the Examiner has not established a proper §102 rejection with regard to Appellant's claim 12. As such, the rejection of independent claim 12, and claims 13-15, 17 and 33-37 depending either directly or indirectly from claim 12, should be reversed.

III. THE BOARD IS URGED TO REVERSE THE THIRD GROUND OF REJECTION: CLAIMS 28-37 ARE PATENTABLE UNDER 35 U.S.C. §103 OVER HERSHBERGER ET AL. (U.S. PAT. 5,470,354).

A. Dependent Claims 28-32

Claims 28-32 depend, directly or indirectly, from independent claim 1.

A proper rejection under §103 has not been established in regard to dependent claims 28-32 for at least the following reason: the Examiner failed to establish a *prima facie* case of obviousness of claims 28-32.

In the first embodiment of Hershberger et al., the sensor component 150 is disclosed as being located on the planar upper surface 92 of the base member 84 of the tibial component. (See Col. 6, lines 53-60). This location is illustrated in FIGS. 5 and 7. Surface 92 of element 84 of Hershberger et al. is described as being "planar" and "flat and smooth" (col. 6, lines 57-66). And where Hershberger et al. illustrate a curved rocker member on the base (see FIGS. 31 and 32, col. 8, lines 15-19 and col. 11, lines 22-25), the opposite member is flat and smooth.

Hershberger et al. teaches use of a flat surface against the sensor/transducer and a curved surface bearing against the flat surface of the sensor/transducer: "The surfaces are flat and smooth in order to provide a satisfactory surface for the force transducer to contact." (col. 6, lines 59-60).

As set forth in MPEP2143.02 VI: "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified the teachings of the references are not sufficient to render the claims *prima facie* obvious." Here the proposed modification – changing a flat surface to a curved surface – also changes the principle of operation of Hershberger et al. With such a modification, it does not appear that rocking of the Hershberger et al. curved component on a flat surface would be possible. Thus, the Examiner has erred in finding the invention of claim 1 to be *prima facie* obvious over

Hershberger et al. Accordingly, the Examiner has erred in finding claims 28-32, which depend from claim 1, to be *prima facie* obvious over Hershberger et al.

Conclusion regarding claims 28-32

Based on the above, the Examiner has not established a proper §103 rejection with regard to Appellant's claims 28-32. As such, the rejection of claims 28-32 should be reversed.

B. Dependent Claims 33-37

Claims 33-37 depend, directly or indirectly, from independent claim 12.

A proper rejection under §103 has not been established in regard to dependent claims 33-37 for at least the following reason: the Examiner failed to establish a *prima facie* case of obviousness of claims 33-37.

In the first embodiment of Hershberger et al., the sensor component 150 is disclosed as being located on the planar upper surface 92 of the base member 84 of the tibial component. (See Col. 6, lines 53-60). This location is illustrated in FIGS. 5 and 7. Surface 92 of element 84 of Hershberger et al. is described as being "planar" and "flat and smooth" (col. 6, lines 57-66). And where Hershberger et al. illustrate a curved rocker member on the base (see FIGS. 31 and 32, col. 8, lines 15-19 and col. 11, lines 22-25), the opposite member is flat and smooth.

Hershberger et al. teaches use of a flat surface against the sensor/transducer and a curved surface bearing against the flat surface of the sensor/transducer: "The surfaces are flat and smooth in order to provide a satisfactory surface for the force transducer to contact." (col. 6, lines 59-60).

As set forth in MPEP2143.02 VI: "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified the

teachings of the references are not sufficient to render the claims *prima facie* obvious." Here the proposed modification – changing a flat surface to a curved surface – also changes the principle of operation of Hershberger et al. With such a modification, it does not appear that rocking of the Hershberger et al. curved component on a flat surface would be possible. Thus, the Examiner has erred in finding the invention of claim 1 to be *prima facie* obvious over Hershberger et al. Accordingly, the Examiner has erred in finding claims 33-37, which depend from claim 12, to be *prima facie* obvious over Hershberger et al.

Conclusion regarding claims 33-37

Based on the above, the Examiner has not established a proper §103 rejection with regard to Appellant's claims 33-37. As such, the rejection of claims 33-37 should be reversed.

IV. SUMMARY CONCLUSIONS

Therefore, in view of the arguments presented above, it is submitted that:

- The rejection of claims 2 and 16 as being unpatentable under 35 USC §112, second paragraph, is erroneous.
- The rejection of claims 1, 3, 4, 10, 12-15 and 17 as being unpatentable under 35 U.S.C. §102 is erroneous.
- The rejection of claims 28-37 as being unpatentable under 35 U.S.C. §103 is erroneous.

The Board is thus urged to reverse this rejection. Such action is respectfully requested.

Respectfully submitted,

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CLAIMS APPENDIX: APPEALED PENDING CLAIMS OF THE PRESENT APPLICATION

1. A modified system for balancing soft tissue intraoperatively during joint arthroplasty, the system being of the type having a first joint trial having an articulating surface having a curved contour, a second joint trial having an articulating surface having a curved contour, the curved contour of the articulating surface of the first joint trial being shaped to receive the articulating surface of the second joint trial, a flexible sensor array capable of being shaped to define a curved contour, the sensor array being capable of generating a signal in response to pressure, and a protector having a surface that has a concave curved contour and an opposite surface that has a convex curved contour, the protector being capable of transmitting pressure to the sensor array, the protector having a thickness between the surface with the concave curved contour and the surface with the convex curved contour, the curved contours of the articulating surface of the first joint trial and the curved contoured surfaces of the protector being curved in a plurality of intersecting cross-sections, the modified system comprising:

complementary mounting members associated with the protector and the first joint trial for temporarily securing the sensor array between the protector and the first joint trial, the complementary mounting members being sized, shaped and positioned so that the protector and the sensor array may be temporarily secured on the curved contour of the articulating surface of the first joint trial with the sensor array positioned between the curved contours of the articulating surface of the first joint trail and the curved contoured opposite surface of the protector;

wherein the sensor array is removable from protector and first joint trial without damaging the sensor array; and

wherein the complementary mounting members limit movement of the protector with respect to the first joint trial in use so that the position of the protector is fixed relative to the articulating surface of the first joint trial during use.

2. A modified system for balancing soft tissue intraoperatively during joint arthroplasty, the system being of the type having a first joint trial having an articulating surface having a curved contour, a second joint trial having an articulating surface, a flexible sensor array capable of being shaped to define a curved contour, the sensor array being capable of generating a signal in response to pressure, and a protector having a curved contoured articulating surface and being capable of transmitting pressure to the sensor array, the modified system comprising:

complementary mounting members associated with the protector and one of the trials for temporarily securing the sensor array between the protector and the trial, the complementary mounting members being positioned so that the protector and the sensor array may be temporarily secured on the curved contour of the articulating surface of the trial;

wherein the sensor array is removable from protector and trial without damaging the sensor array; and

wherein the complementary mounting members limit movement of the protector with respect to the associated trial in use so that the position of the articulating surface of the protector is fixed relative to the articulating surface of the associated trial during use; and

wherein the protector comprises a first portion and a second portion joined along an axis, and wherein the first portion of the protector overlies at least a part of the curved contour of the articulating surface of the first trial and the second portion overlies at least a substantial part of the sensor array and at least a substantial part of the first portion of the protector.

3. The modified system of claim 1 wherein the complementary mounting members comprise a stud and an aperture.

4. The modified system of claim 1 wherein the complementary mounting members are sized, shaped and positioned to allow the first joint trial and protector to be snap fit together to temporarily combine the protector, sensor array and first joint trial into an assembly for use.

10. A modified system for balancing soft tissue intraoperatively during joint arthroplasty, the system being of the type having a first joint trial having an articulating surface with a curved concave contour and a surface adjacent to the curved concave articulating surface, a second joint trial having an articulating surface with a curved convex contour, a flexible sensor array shaped to define a curved concave contour, the sensor array being capable of generating a signal in response to pressure, and a protector having a surface with a curved concave contour and a surface with a curved convex contour and being capable of transmitting pressure to the sensor array, the curved convex surface of the protector overlying and contacting at least a substantial part of the curved concave contour of the flexible sensor array, the curved concave surface of the protector being exposed above the sensor, the flexible sensor array, the articulating surface of the first joint trial, the curved concave surface of the protector and the curved convex surface of the protector being curved in a plurality of intersection cross-sections, the modified system comprising:

a stud extending between the protector and the surface adjacent the curved concave articulating surface of the first joint trial for temporarily fixing the position of at least part of the protector with respect to the trial.

12. A modified system for balancing soft tissue intraoperatively during joint arthroplasty, the system being of the type including a first joint trial having an articulating surface having a curved contour, a second joint trial having an articulating surface having a curved contour, a flexible sensor array associated with one of the trials and having a portion shaped to define a curved contour, the sensor array being capable of generating a signal in response to pressure, and a protector having a surface with a curved concave contour and a surface with a curved convex contour and being capable of transmitting pressure to the sensor array, the protector having a thickness between the curved concave contour and the curved convex contour, the thickness of the protector at the curved contoured surfaces being less than half the thickness of the first joint trial at the articulating surface, the sensor array being positioned between the curved contour of the articulating surface of the first joint trial and the curved contoured surfaces of the protector, the curved contour of the articulating surface of the first joint trial and the curved contoured surfaces of the protector being curved in a plurality of intersecting cross-sections, the modified system characterized in that:

positive locating features are provided so that the sensor array is positively located with respect to at least one of the protector and the first trial; and

the sensor array is separable from the associated trial and the protector both before and after use;

wherein the positive locating features include at least one positive locating feature spaced from the curved contour of the articulating surface of the first joint trial.

13. The modified system of claim 12 wherein the protector and at least one of the joint trials have complementary mounting members.

14. The modified system of claim 13 wherein the complementary mounting members comprise a recess and a protrusion.

15. The modified system of claim 13 wherein the complementary mounting members comprise an aperture and a stud so that the protector can be snap fit to the trial.

16. A modified system for balancing soft tissue intraoperatively during joint arthroplasty, the system being of the type including a first joint trial having an articulating surface having a curved contour, a second joint trial having an articulating surface, a flexible sensor array associated with one of the trials and being shaped to define a curved contour, the sensor array being capable of generating a signal in response to pressure, and a protector having a curved contoured surface and being capable of transmitting pressure to the sensor array, the sensor array being positioned between the curved contour of the articulating surface of the first joint trial and the curved contoured surface of the protector, the modified system characterized in that:

the sensor array is positively located with respect to at least one of the protector and the first trial; and

the sensor array is separable from the associated trial and the protector both before and after use;

wherein the protector has a first portion and a second portion joined along an axis, wherein the first portion of the protector overlies at least part of the curved contour of the articulating surface of the first trial and the second portion overlies at least a substantial part of the sensor array and a substantial part of the first portion of the protector.

17. The modified system of claim 12 wherein the protector is capable of being snap fit to one of the first joint trial to temporarily combine the protector, sensor array and first joint trial into an assembly for use.

28. The modified system of claim 1 wherein the articulating surface of the first joint trial is concave and the articulating surface of the second joint trial is convex and wherein the complementary mounting members are spaced from the articulating surface of the first joint trial and the articulating surface of the protector.

29. The modified system of claim 28 wherein the first joint trial includes an additional surface adjacent to the concave articulating surface of the first joint trial and wherein one of the complementary mounting members is associated with the additional surface of the first joint trial.

30. The modified system of claim 29 wherein the first joint trial includes a second concave articulating surface and the additional surface adjacent to the concave articulating surface is between the two articulating surfaces of the first joint trial.

31. The modified system of claim 1 wherein the articulating surfaces of the first joint trial and the protector are convex and the articulating surface of the second joint trial is concave and wherein the complementary mounting members are spaced from the articulating surfaces of the first joint trial and the articulating surface of the protector.

32. The modified system of claim 31 wherein the first joint trial has a periphery and the protector has a periphery and the complementary mounting members are associated with the peripheries of the first joint trial and the protector.

33. The modified system of claim 12 wherein the articulating surfaces of the first joint trial and the protector are concave and the articulating surface of the second joint trial is convex and wherein the mating members are spaced from the concave articulating surfaces of the first joint trial and the articulating surface of the protector.

34. The modified system of claim 33 wherein the first joint trial includes an additional surface adjacent to the concave articulating surface of the first joint trial and wherein one of the mating members is associated with the additional surface of the first joint trial.

35. The modified system of claim 34 wherein the first joint trial includes a second concave articulating surface and the additional surface adjacent to the concave articulating surface is between the two articulating surfaces of the first joint trial.

36. The modified system of claim 12 wherein the articulating surfaces of the first joint trial and the protector are convex and the articulating surface of the second joint trial is concave and wherein the mating members are spaced from the articulating surfaces of the first joint trial and the protector.

37. The modified system of claim 36 wherein the first joint trial has a periphery and the protector has a periphery and the mating members are associated with the peripheries of the first joint trial and the protector.

EVIDENCE APPENDIX

Nothing is included with this appendix.

RELATED PROCEEDINGS APPENDIX

Nothing is included with this appendix.